IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(Northern Division)

BAYER SCHERING PHARMA AG,
Müllerstrasse 178
13353 Berlin, Germany,

BAYER HEALTHCARE
PHARMACEUTICALS INC.,
340 Changebridge Road
P.O. Box 1000
Montville, NJ 07045-1000,

and

SCHERING CORPORATION,
2000 Galloping Hill Road
Kenilworth, NJ 07033,

Plaintiffs,

v.

Civil Action No. _____

LUPIN LTD.,
B/4 Laxmi Towers
Bandra-Kurla Complex
Bandra (W)
Mumbai 400 051, India

and

LUPIN PHARMACEUTICALS, INC.,
Harborplace Tower
111 South Calvert Street
Baltimore, MD 21202
Baltimore City

Defendants.

COMPLAINT

Plaintiffs Bayer Schering Pharma AG, Bayer HealthCare Pharmaceuticals Inc., and Schering Corporation (collectively "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of Lupin Ltd.'s and Lupin Pharmaceuticals, Inc.'s (collectively, "Lupin") submission of Abbreviated New Drug Application ("ANDA") No. 200-563 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Cipro® Oral Suspension prior to the expiration of U.S. Patent No. 5,695,784.

PARTIES

2. Plaintiff Bayer Schering Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with its principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

3. Plaintiff Bayer HealthCare Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

4. Plaintiff Schering Corporation is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

5. On information and belief, Lupin Ltd. is an Indian corporation having a place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (W), Mumbai 400 051, India, and having a registered office at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098,

India. On information and belief, Lupin Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products through various operating subsidiaries, including Lupin Pharmaceuticals, Inc.

6. On information and belief, Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland, 21202. On information and belief, Lupin Pharmaceuticals, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market. On information and belief, Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary and alter-ego of Lupin Ltd.

7. On information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 200-563, Lupin Ltd. and Lupin Pharmaceuticals, Inc., will act in concert to distribute and sell Lupin's Ciprofloxacin Oral Suspension, 250 mg/5 mL ("Lupin's 250 mg/5 mL ANDA Product") and 500 mg/5mL ("Lupin's 500 mg/5 mL ANDA Product") throughout the United States, including within Maryland. These products will be referred to collectively herein as "Lupin's ANDA Products." On information and belief, following any FDA approval of ANDA No. 200-563, Lupin Ltd. and Lupin Pharmaceuticals, Inc. know and intend that Lupin's ANDA Products will be distributed and sold in the United States, including within Maryland.

8. On information and belief, and consistent with their practice with respect to other generic products, Lupin Ltd. and Lupin Pharmaceuticals, Inc., acted in concert to prepare and submit ANDA No. 200-563. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals, Inc., actively participated in the preparation of ANDA No. 200-563 and both

entities submitted it to the FDA. On information and belief, Lupin Pharmaceuticals, Inc., acted as the agent of Lupin Ltd. in submitting ANDA No. 200-563 to the FDA.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

10. On information and belief, Lupin Ltd. is subject to personal jurisdiction in Maryland because, among other things, Lupin Ltd., itself and through its wholly-owned subsidiary Lupin Pharmaceuticals, Inc., has purposely availed itself of the benefits and protections of Maryland's laws such that it should reasonably anticipate being haled into court here, and because Lupin Ltd. established the principal place of business of its wholly-owned subsidiary Lupin Pharmaceuticals, Inc., in Maryland. On information and belief, Lupin Ltd., itself and through its wholly-owned subsidiary Lupin Pharmaceuticals, Inc., manufactures, markets and sells generic drugs throughout the United States and within the State of Maryland and therefore transacts business within the State of Maryland related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Maryland. Lupin Ltd. is subject to jurisdiction in Maryland on the basis of its inducement of and/or contribution to Lupin Pharmaceuticals, Inc.'s acts of infringement in Maryland. In addition, Lupin Ltd. is subject to personal jurisdiction in Maryland because, on information and belief, it controls and dominates Lupin Pharmaceuticals, Inc. and therefore the activities of Lupin Pharmaceuticals, Inc., in this jurisdiction are attributed to Lupin Ltd.

11. On information and belief, this Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. because Lupin Pharmaceuticals, Inc. has its principal place of business in Maryland, is a resident and citizen thereof, has purposely availed itself of the benefits and

protections of Maryland's laws such that it should reasonably anticipate being haled into court here. On information and belief, Lupin Pharmaceuticals, Inc. manufactures, markets and sells generic drugs throughout the United States and within the State of Maryland and therefore transacts business within the State of Maryland related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Maryland.

12. In addition, this Court has personal jurisdiction over Lupin Ltd. and Lupin Pharmaceuticals, Inc. because Lupin Ltd. and Lupin Pharmaceuticals, Inc. have consented to jurisdiction in this judicial district in previous litigation and because Lupin Ltd. and Lupin Pharmaceuticals, Inc. have affirmatively availed themselves of the Courts of this district by filing claims in this district.

13. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b)–(d) and 1400(b).

BACKGROUND

14. Cipro® Oral Suspension ("Cipro® OS") is an oral suspension containing, as the active ingredient, ciprofloxacin. Cipro® OS is indicated for the treatment of infections caused by susceptible strains of designated microorganisms in certain conditions and patient populations. Cipro® OS is supplied in strengths of 250 mg/5 mL and 500 mg/5 mL.

15. United States Patent No. 5,695,784 ("the '784 patent"), entitled "Flavor-Masked Pharmaceutical Compositions," was duly and legally issued on December 9, 1997, to Bayer Aktiengesellschaft as assignee of Norbert Pöllinger, Johannes Michaelis, Klaus Benke, Roland Rupp, and Manfred Bücheler. The '784 patent is attached as Exhibit A hereto.

16. The '784 patent has been subsequently assigned to Bayer Schering Pharma AG.

17. Bayer HealthCare Pharmaceuticals Inc. is the holder of New Drug Application No. 20-780 for Cipro® OS, which has been approved by the U.S. Food and Drug Administration. Pursuant to 21 U.S.C. § 355, the '784 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with Cipro® OS.

18. Schering Corporation has been granted an exclusive license under the '784 patent and sells Cipro® OS in the United States.

19. By letter dated January 5, 2010 (the "Notice Letter"), Lupin notified, *inter alia*, Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc. that Lupin had submitted to the FDA ANDA No. 200-563 for Lupin's ANDA Products. Lupin's ANDA Products are generic versions of Cipro® OS. The purpose of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, and/or sale of Lupin's ANDA Products within the United States prior to the expiration of the '784 patent.

20. In the Notice Letter, Lupin also stated that, as part of its ANDA, Lupin had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '784 patent. Upon information and belief, Lupin submitted ANDA No. 200-563 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '784 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, import, use, offer for sale, and/or sale of Lupin's ANDA Products.

21. The claim of the '784 patent, incorporated by reference herein, covers Cipro® OS.

22. In the Notice Letter, Lupin notified Bayer Schering Pharma AG and Bayer

23. Lupin had knowledge of the ’784 patent prior to its filing of ANDA No. 200-563.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 5,695,784 BY LUPIN’S 250 mg/5 mL ANDA PRODUCT

24. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

25. Lupin’s submission of ANDA No. 200-563 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Lupin’s 250 mg/5mL ANDA Product within the United States before the expiration of the ’784 patent was an act of infringement of the ’784 patent under 35 U.S.C. § 271(e)(2)(A).

26. Upon information and belief, Lupin has acted with full knowledge of the ’784 patent and without a reasonable basis for believing that it would not be liable for infringing the ’784 patent.

27. Unless Lupin is enjoined from infringing the ’784 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 5,695,784 BY LUPIN’S 250 mg/5 mL ANDA PRODUCT

28. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

29. Upon information and belief, Lupin will engage in the manufacture, use, offer for sale, sale, marketing, and/or distribution within the United States, and/or the

importation into the United States, of Lupin's 250 mg/5 mL ANDA Product immediately and imminently upon approval of ANDA No. 200-563.

30. The manufacture, use, offer for sale, sale, marketing, and/or distribution within the United States, and/or importation into the United States, of Lupin's 250 mg/5 mL ANDA Product would infringe one or more claims of '784 patent.

31. Upon information and belief, Lupin will engage in the manufacture, use, offer for sale, sale, marketing, and/or distribution within the United States, and/or importation into the United States, of Lupin's 250 mg/5 mL ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 200-563.

32. Upon information and belief, use of Lupin's 250 mg/5 mL ANDA Product within the United States in accordance with and as directed by Lupin's proposed labeling for that product would infringe one or more claims of the '784 patent.

33. Upon information and belief, Lupin plans and intends to, and will, actively induce infringement of the '784 patent when ANDA No. 200-563 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

34. Upon information and belief, Lupin knows that Lupin's 250 mg/5 mL ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '784 patent, and that Lupin's 250 mg/5 mL ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Lupin plans and intends to, and will, contribute to infringement of the '784 patent immediately and imminently upon approval of ANDA No. 200-563.

35. The foregoing actions by Lupin constitute and/or will constitute infringement of the '784 patent, active inducement of infringement of the '784 patent, and

contribution to the infringement by others of the ’784 patent.

36. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Lupin on the other hand regarding Lupin’s infringement of the ’784 patent, active inducement of infringement of the ’784 patent, and contribution to the infringement by others of the ’784 patent.

37. Plaintiffs are entitled to a judgment declaring that the foregoing actions by Lupin constitute and/or will constitute infringement of the ’784 patent, active inducement of infringement of the ’784 patent, and contribution to the infringement by others of the ’784 patent.

38. Upon information and belief, Lupin has acted with full knowledge of the ’784 patent and without a reasonable basis for believing that it would not be liable for infringing the ’784 patent, actively inducing infringement of the ’784 patent, and contributing to the infringement by others of the ’784 patent.

39. Unless Lupin is enjoined from infringing the ’784 patent, actively inducing infringement of the ’784 patent, and contributing to the infringement by others of the ’784 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT III – INFRINGEMENT OF U.S. PATENT NO. 5,695,784 BY LUPIN’S 500 mg/5 mL ANDA PRODUCT

40. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

41. Lupin’s submission of ANDA No. 200-563 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Lupin’s 500 mg/5 mL ANDA Product within the United States before the expiration of the ’784 patent was an

act of infringement of the ’784 patent under 35 U.S.C. § 271(e)(2)(A).

42. Upon information and belief, Lupin has acted with full knowledge of the ’784 patent and without a reasonable basis for believing that it would not be liable for infringing the ’784 patent.

43. Unless Lupin is enjoined from infringing the ’784 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 5,695,784 BY LUPIN’S 500 mg/5 mL ANDA PRODUCT

44. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

45. Upon information and belief, Lupin will engage in the manufacture, use, offer for sale, sale, marketing, and/or distribution within the United States, and/or importation into the United States, of Lupin’s 500 mg/5 mL ANDA Product immediately and imminently upon approval of ANDA No. 200-563.

46. The manufacture, use, offer for sale, sale, marketing, and/or distribution within the United States, and/or importation into the United States, of Lupin’s 500 mg/5 mL ANDA Product would infringe one or more claims of ’784 patent.

47. Upon information and belief, Lupin will engage in the manufacture, use, offer for sale, sale, marketing, and/or distribution within the United States, and/or importation into the United States, of Lupin’s 500 mg/5 mL ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 200-563.

48. Upon information and belief, use of Lupin’s 500 mg/5 mL ANDA Product within the United States in accordance with and as directed by Lupin’s proposed labeling for that product would infringe one or more claims of the ’784 patent.

49. Upon information and belief, Lupin plans and intends to, and will, actively induce infringement of the ’784 patent when ANDA No. 200-563 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

50. Upon information and belief, Lupin knows that Lupin’s 500 mg/5 mL ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’784 patent, and that Lupin’s 500 mg/5 mL ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Lupin plans and intends to, and will, contribute to infringement of the ’784 patent immediately and imminently upon approval of ANDA No. 200-563.

51. The foregoing actions by Lupin constitute and/or will constitute infringement of the ’784 patent, active inducement of infringement of the ’784 patent, and contribution to the infringement by others of the ’784 patent.

52. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Lupin on the other hand regarding Lupin’s infringement of the ’784 patent, active inducement of infringement of the ’784 patent, and contribution to the infringement by others of the ’784 patent.

53. Plaintiffs are entitled to a judgment declaring that the foregoing actions by Lupin constitute and/or will constitute infringement of the ’784 patent, active inducement of infringement of the ’784 patent, and contribution to the infringement by others of the ’784 patent.

54. Upon information and belief, Lupin has acted with full knowledge of the ’784 patent and without a reasonable basis for believing that it would not be liable for infringing

the ’784 patent, actively inducing infringement of the ’784 patent, and contributing to the infringement by others of the ’784 patent.

55. Unless Lupin is enjoined from infringing the ’784 patent, actively inducing infringement of the ’784 patent, and contributing to the infringement by others of the ’784 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Lupin has infringed the ’784 patent;

(b) A judgment ordering that the effective date of any FDA approval for Lupin to make, use, offer for sale, sell, market, distribute, or import Lupin’s ANDA Products, or any product that infringes the ’784 patent, be not earlier than the expiration date of the ’784 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Lupin, and all persons acting in concert with Lupin, from making, using, selling, offering for sale, marketing, distributing, or importing Lupin’s ANDA Products, or any product that infringes the ’784 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the ’784 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Lupin’s ANDA Products, or any product that infringes the ’784 patent, prior to the expiration date of the ’784 patent, will infringe, actively induce infringement of, and contribute to the infringement by others of the ’784 patent;

(e) A declaration that this is an exceptional case and an award of attorneys’ fees pursuant to 35 U.S.C. § 285;

(f) An award of Plaintiffs’ costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

Respectfully submitted,

/s/

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